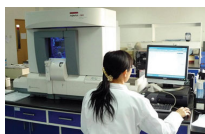


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**Feature Article**

## **Innovative Drug R&D on the Rise in China** **Technically Savvy Returnees, Influx of VC Funding, and Solid Government Support Buoy Efforts**

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**Chinese pharma and biotech firms like Joynn Laboratories have improved their research and development capabilities in recent years.**

As the Chinese pharmaceutical industry expands rapidly, Chinese pharma and biotech companies—and even outsourcing service providers—are increasingly paying attention to and investing in innovative drug R&D. A flotilla of returnees and venture capital firms are aiding in these endeavors.

Unfortunately, innovative R&D activities in China remain largely unknown to many outside country. Outsiders are also oblivious to the scope and scale of research, research capability, and robust product pipelines in the fast-growing country. This article will describe the current R&D situation in China and discuss the future development potential.

Up to this point, innovative R&D in China has been almost nonexistent, largely due to the modern pharmaceutical industry's short history. It was not long ago that almost all Chinese pharmaceutical companies manufactured off-patent drugs. These days, as a result of two decades of sustained economic growth, the country is finally conducting innovative research.

The importance of innovative R&D has been well recognized nationwide. Government at all levels is encouraging research on novel medicines and promises to provide all necessary support. Government grants and venture capital are now more readily available; venture capital investors recently emerged in China or entered the Chinese market from other countries.

Research institutes and universities, which used to be the nation's R&D powerhouses, have received even more funding. R&D-focused biotech companies are proliferating. The environment is also being buttressed by multinational drug companies that have set up wholly-owned R&D divisions in China, and conduct innovative research locally.

## **Industry Composition**

There are three groups of companies playing key roles in the Chinese pharmaceutical industry. The first group consists of young, R&D-oriented biotech companies. They are currently responsible for much of China's innovative R&D. Among all R&D companies we surveyed, close to 60% of them were recently founded by Chinese returnee entrepreneurs. We also identified a small number of China-based outsourcing service providers (mainly top-tier CROs) that are conducting innovative R&D internally.

The second group is composed of major Chinese pharma companies. Among the more than 5,000 registered Chinese pharma companies, only a small fraction (<1%) are currently conducting truly innovative R&D. Many companies, though claiming to have research programs, actually focus on areas such as generic drug development and production process improvement. Most of these major Chinese pharma companies spend only about 3–5% of their sales revenues on R&D. A small fraction of them (about 5–10%) have annual R&D expenditures of about 5–8%.

The third group includes top-tier state-owned research institutions including universities that have life-science schools/departments. In recent years, the Chinese government has significantly increased R&D budgets at state-owned research institutes and top-tier research universities. Since 1994, 15 state-owned biomedical research centers (called National Key Labs) have been created, all located within the top-tier research institutions. Most of them are well equipped and have recruited experienced researchers from the West. At present, however, only a handful of them are engaged in innovative research, the majority are focused on basic medical research.

## **Product Pipelines**

Chinese pharma and biotech firms have dramatically improved their innovative R&D capabilities in recent years. Their current areas of expertise include small molecule-based and macro compound-based drugs. Small molecule programs are focused mainly on traditional Chinese medicines (TCMs). Their research methodologies for novel biologic drugs are, however, more diverse and advanced, including all types of biologically derived proteins.

The recent efforts of Chinese drug companies are starting to pay off, and there are currently a number of drug candidates in various stages of development for a broad range of therapeutic targets. According to our survey results, nearly 65% of drug candidates are in early development stages (either preclinical or Phase I trials). However, about 14% of

novel medicines—mostly new TCMs and vaccines—have proceeded to the advanced development stages and some have been approved for marketing.

About 42% of Chinese R&D firms have a cancer focus. In addition, cancer drugs based on a variety of treatment mechanisms represent the largest group of drug candidates among the surveyed companies.

Unlike the Western pharma industry, R&D collaborations between major Chinese pharma and biotech companies are rare. Major Chinese pharma companies do not rely on biotech companies to fill their pipelines.

In contrast, largely attracted by the growth potential of China's pharmaceutical market, large talent pool, and still-low cost labor, growing numbers of pharma and biotech companies from around the world are conducting innovative R&D in China or collaborating with local Chinese drug companies. Collaborative research is being conducted in a myriad of areas, including cancer drugs, drug-delivery, molecular diagnostic and imaging tools, biomarkers, stem cells, and RNA interference.

Unfortunately, however, due to China's lack of experience with innovative R&D, there are a number of limitations in the industry. One major issue is that the majority of Chinese drug companies do not have a sufficiently large, experienced technical team whose combined expertise could span the entire value chain of discovery and development.

The Chinese government is serious in its quest to dramatically boost the nation's innovative R&D capabilities. The central government recently outlined a plan to launch 30 new drugs in the Chinese market by 2020 that are developed entirely by Chinese companies. To this end, the government aims to have close to 100 drug candidates by the end of 2010 that will have completed preclinical development and be ready to enter clinical development.

To help Chinese companies reach these goals, the government will financially support research particularly in areas like identification and validation of therapeutic targets, lead discovery and optimization, and preclinical research. It will also encourage companies to focus on the development of innovative drugs in such therapeutic areas as cancer, cardiovascular disease, diabetes, autoimmune-related disease, viral infections, TB, and neurodegenerative diseases, as well as novel antibiotics against drug-resistant bacteria.

Government funding will also support the development of new formulation and drug-delivery technologies such as those for controlled-release delivery. In addition, the government will encourage companies to improve their production and quality-control techniques. Through steady but heavy investment, the government intends to establish eight technical platforms covering almost the entire value chain of innovative R&D and manufacturing processes.

## **Predictions for the Future**

In terms of both research capability and scale of the industry, innovative R&D in China is just beginning. The industry has achieved extraordinary momentum, however. Driven by strong government support and readily available R&D funding, coupled with the gradual maturation of exit channels for venture capital firms, innovative R&D in China is expected to grow at a much faster pace in the coming years. Novel drugs completely discovered by Chinese companies will soon be marketed worldwide, even in the well-regulated Western markets.

The still-low labor and material costs in China make the country's products relatively inexpensive and thus more attractive. Western companies can often save a substantial amount of money by licensing potentially promising drug candidates from Chinese firms. It can therefore be expected that an increasing number of Western drug companies will enter the Chinese industry shortly. The growing interest of experienced drug companies should in turn further accelerate the growth of innovative drug R&D in China.

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